



[Billing Code 4140-01-P]

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### **International Workshop on Alternative Methods for *Leptospira* Vaccine Potency Testing: State of the Science and the Way Forward**

**AGENCY:** Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH)

**ACTION:** Announcement of a Workshop; Call for Abstract Submissions

**SUMMARY:** The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces an “International Workshop on Alternative Methods for *Leptospira* Vaccine Potency Testing: State of the Science and the Way Forward.” This workshop, the second in a series of specialized vaccine workshops, will review recent advances and innovations in science and technology that can be applied to *Leptospira* vaccine potency testing. The goal is to promote development of innovative testing methods and approaches that may provide improved accuracy, efficiency, and worker safety and that are more humane and use fewer or no animals. The workshop will also address global acceptance and implementation of scientifically valid alternative methods.

The workshop is open to the public at no charge with attendance limited only by the available space; however, advance registration is required (see DATES). NICEATM also invites submission of abstracts for scientific posters for display at the workshop (see SUPPLEMENTARY INFORMATION).

**DATES:** The workshop is scheduled for September 19–21, 2012. Sessions will begin at 1:00 p.m. CDT on September 19 and 8:00 a.m. on September 20 and 21. Sessions will end at approximately 6:00 p.m. on September 19 and 20 and at 1:00 p.m. on September 21. The deadline for registration is September 7, 2012. Due to U.S. Department of Agriculture (USDA) security requirements, onsite registration at the workshop will not be available. The deadline for submission of poster abstracts is August 13, 2012.

**ADDRESSES:** The workshop will be held at the USDA Center for Veterinary Biologics at the National Centers for Animal Health, 1920 Dayton Avenue, Ames, Iowa 50010. Individuals with disabilities who need accommodation to participate in this event should contact Ms. Debbie McCarley at voice telephone: 919-541-2384 or email: [mccarley@niehs.nih.gov](mailto:mccarley@niehs.nih.gov). TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least 5 business days in advance of the event.

**FOR FURTHER INFORMATION CONTACT:** Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2–16, Research Triangle Park, NC, 27709, (telephone) 919-541-2384, (fax) 919-541-0947, (email) [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov). Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

## **SUPPLEMENTARY INFORMATION:**

### **Background**

Leptospirosis is an emerging and widespread bacterial zoonotic disease caused by spirochetes of the genus *Leptospira*. An estimated 500,000 human cases of leptospirosis occur worldwide each year, with a fatality rate of up to 25% in some regions. Designated a Neglected Tropical Disease by the NIH and a Neglected Zoonotic Disease by the World Health Organization, leptospirosis is a global research and public health priority.

Leptospirosis affects numerous animal species including livestock, pets, and wildlife. Vaccines have been developed for most susceptible livestock and domestic pet species and are widely used in the U.S. and other countries. Human *Leptospira* vaccines that protect against region-specific serovars are also available for workers in high-risk professions in selected countries, although none are currently approved for use in the United States.

Regulatory authorities require potency testing prior to release of each production lot of *Leptospira* vaccine to ensure that it will be effective. However, the current testing methods require the use of large numbers of laboratory animals that experience significant unrelieved pain and distress, accounting for over one-third of the animals reported to the USDA in this pain category. A recent international workshop, organized by NICEATM, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), and their international partners, identified *Leptospira* vaccines as one of the three highest priorities for future research, development, and validation of alternative test methods that could further reduce, refine (enhance animal well-being and lessen or avoid pain and distress), or replace animal use for vaccine potency testing (Stokes et al., 2011). The USDA has developed and validated *in vitro* enzyme-linked immunosorbent assay (ELISA) antigen quantification methods for potency determination of vaccines for several *Leptospira* serovars (i.e., *Leptospira interrogans* serovars *pomona*, *canicola*, *icterohaemorrhagiae*, and *Leptospira kirschneri* serovar *grippotyphosa* [Kulpa-Eddy, 2012; USDA, 2009a, 2009b, 2009c, 2011]).

This workshop, the second in a series of specialized vaccine workshops, will review recent advances and innovations in science and technology that can be applied to the development of new methods and approaches for *Leptospira* vaccine potency testing. These new methods and approaches may provide improved accuracy, efficiency, and worker safety, and

would be more humane and use fewer or no animals. Participants will develop a strategy to achieve global acceptance and implementation of scientifically valid alternative methods.

NICEATM and ICCVAM are organizing the workshop in collaboration with partner organizations in the International Cooperation on Alternative Test Methods (ICATM): the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM), the Japanese Center for the Validation of Alternative Methods, the Korean Center for the Validation of Alternative Methods, and Health Canada. Cosponsors include EURL ECVAM, the Animal Health Institute, the International Alliance for Biological Standardization, and the USDA Center for Veterinary Biologics.

### **Preliminary Workshop Agenda and Registration**

Registration information, draft agenda, and additional meeting information are available on the NICEATM–ICCVAM website (<http://iccvam.niehs.nih.gov/meetings/LeptoVaccWksp-2012/LeptoVaccWksp.htm>) and upon request from NICEATM (see FOR FURTHER INFORMATION CONTACT).

### **Call for Abstract Submissions**

NICEATM and ICCVAM invite the submission of abstracts for scientific posters to be displayed during this workshop. Guidelines for the submission of abstracts are available at <http://iccvam.niehs.nih.gov/meetings/LeptoVaccWksp-2012/LeptoWksp-AbstractSubmit-508.pdf>. Abstracts must be submitted by email to [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov). The deadline for abstract submission is August 13, 2012. The corresponding author will be notified regarding the abstract's acceptance within 7 working days of the submission deadline. Guidelines for poster presentations will be sent to the corresponding authors with notification of acceptances.

## **Background Information on NICEATM and ICCVAM**

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine, or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies applicable to the needs of U.S. Federal agencies. Additional information about ICCVAM and NICEATM can be found on the NICEATM-ICCVAM website (<http://iccvam.niehs.nih.gov>).

## **References**

Kulpa-Eddy J. 2012. Successful Development and Validation of an *In Vitro* Replacement Assay for *Leptospira* Vaccine Potency Tests. In: Proceedings of an International Scientific Workshop on Potency Testing of Veterinary Vaccines for Animals: The Way from *In Vivo* to *In Vitro*; Langen, Germany; 1–3 December 2010 (Jungbäck, C, ed.). Basel: Karger.

USDA. 2009a. SAM 624: Supplemental Assay Method for *In Vitro* Potency Testing of *Leptospira interrogans* Serovar *pomona* Bacterins. Washington, DC:USDA Animal and Plant

Health Inspection Service. Available:

[http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/vb\\_sams\\_600\\_series.shtml](http://www.aphis.usda.gov/animal_health/vet_biologics/vb_sams_600_series.shtml).

USDA. 2009b. SAM 625: Supplemental Assay Method for *In Vitro* Potency Testing of *Leptospira interrogans* Serovar *canicola* Bacterins. Washington, DC:USDA Animal and Plant Health Inspection Service. Available:

[http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/vb\\_sams\\_600\\_series.shtml](http://www.aphis.usda.gov/animal_health/vet_biologics/vb_sams_600_series.shtml).

USDA. 2009c. SAM 627: Supplemental Assay Method for *In Vitro* Potency Testing of *Leptospira interrogans* Serovar *icterohaemorrhagiae* Bacterins. Washington, DC:USDA Animal and Plant Health Inspection Service. Available:

[http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/vb\\_sams\\_600\\_series.shtml](http://www.aphis.usda.gov/animal_health/vet_biologics/vb_sams_600_series.shtml).

USDA. 2011. SAM 626: Supplemental Assay Method for *In Vitro* Potency Testing of *Leptospira kirschneri* serogroup *grippotyphosa* Bacterins. Washington, DC:USDA Animal and Plant Health Inspection Service. Available:

[http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/vb\\_sams\\_600\\_series.shtml](http://www.aphis.usda.gov/animal_health/vet_biologics/vb_sams_600_series.shtml).

Stokes WS, Kulpa-Eddy J, McFarland R. 2011. The International Workshop on Alternative Methods to Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing: introduction and summary. In: International Workshop on Alternative Methods to Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing: State of the Science and Future Directions (Kulpa-Eddy J, McFarland R, Stokes WS, eds). *Procedia Vaccinol* 5: 1-15.

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